

Complete Summary

GUIDELINE TITLE

Treatment: fluid resuscitation. In: Guidelines for the prehospital management of severe traumatic brain injury, second edition.

BIBLIOGRAPHIC SOURCE(S)

Treatment: fluid resuscitation. In: Badjatia N, Carney N, Crocco TJ, Fallat ME, Hennes HM, Jagoda AS, Jernigan S, Lerner EB, Letarte PB, Moriarty T, Pons PT, Sasser S, Scalea TM, Schleien C, Wright DW. Guidelines for prehospital management of traumatic brain injury. 2nd ed. New York (NY): Brain Trauma Foundation; 2007. p. 61-70. [21 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Brain Trauma Foundation. Guidelines for prehospital management of traumatic brain injury. New York (NY): Brain Trauma Foundation; 2000. 81 p.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT
CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

- Traumatic brain injury (TBI)
- Hypotension

GUIDELINE CATEGORY

Evaluation
Management
Treatment

CLINICAL SPECIALTY

Critical Care
Emergency Medicine
Neurological Surgery
Neurology
Pediatrics

INTENDED USERS

Emergency Medical Technicians/Paramedics
Physicians

GUIDELINE OBJECTIVE(S)

- To provide guidelines for the early and appropriate prehospital management of traumatic brain injury (TBI)
- To provide guidance on properly identifying and treating patients with TBI who need fluid resuscitation

TARGET POPULATION

Adults and children with traumatic brain injury

INTERVENTIONS AND PRACTICES CONSIDERED

Hypertonic versus isotonic fluid resuscitation

MAJOR OUTCOMES CONSIDERED

- Morbidity and mortality from traumatic brain injury (TBI)
- Positive predictive value of hypotension for worsened outcome

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

General Search Strategy

Four participants were assigned to work on each topic – two for the adult section and two for the pediatric section. Participants finalized the scope of each topic and provided terms for the electronic literature search.

Inclusion Criteria

- Human subjects
- Traumatic brain injury (TBI)
- English language
- ≥ 25 subjects
- Randomized controlled trials (RCTs), cohort studies, case-control studies, case series, databases, registries

Exclusion Criteria

- Sample contained >15% of pediatric patients, or >15% of patients with pathologies other than TBI AND the data were not reported separately (see Appendix C)
- Wrong independent variable (e.g., the intervention was not specific to the topic)
- Wrong dependent variable (e.g., outcomes were not mortality or morbidity, or did not associate with clinical outcomes)
- Statistics used in the analysis were not appropriate to the research design, variables, and/or sample size case studies, editorials, comments, letters

Center staff worked with a doctoral-level research librarian to construct electronic search strategies for each topic from 1996 through April of 2005 to August 2005 (see Appendix B in the original guideline document). They used strategies with the highest likelihood of capturing most of the targeted literature, which resulted in the acquisition of a large proportion of non-relevant citations. A set of abstracts was sent to the participants for each topic. Blinded to each others' work, they read the abstracts and eliminated citations using the criteria specified above.

Center staff compared the participants' selections, identified discrepancies, and worked with authors to resolve them. A set of full-text publications was sent to each participant. They read the publications and determined the final library of studies that would be used as evidence. Results of the electronic searches were supplemented by recommendations of peers and by reading reference lists of included studies.

A second search was conducted from 2005 through July of 2006 to capture any relevant Class I or II literature that might have been published since the first literature search in 2005. Relevant publications were added to those from the original search, constituting the final library of studies that were used as evidence in this document. The yield of literature from each phase of the search is presented in Appendix D in the original guideline document.

Specific Strategy for This Topic

For this update Medline was searched from 1996 through July 2006 using the search strategy for this question (see Appendix B in the original guideline

document), and results were supplemented with literature recommended by peers or identified from reference lists. For adult studies, of 15 potentially relevant publications, 1 was added to the existing table and used as evidence for this question. For pediatric studies, of 23 potentially relevant publications, no new studies were included (see Evidence Tables in the original guideline document).

NUMBER OF SOURCE DOCUMENTS

8 adult studies and 8 pediatric studies

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Class of Evidence	Study Design	Quality Criteria
I	Good quality randomized controlled trial (RCT)	<p>Adequate random assignment method.</p> <p>Allocation concealment.</p> <p>Groups similar at baseline.</p> <p>Outcome assessors blinded.</p> <p>Adequate sample size.</p> <p>Intention-to-treat analysis.</p> <p>Follow-up rate $\geq 85\%$.</p> <p>Differential loss to follow-up.</p> <p>Maintenance of comparable groups.</p>
II	Moderate quality RCT	Violation of one or more of the

Class of Evidence	Study Design	Quality Criteria
		criteria for a good quality RCT. ¹
II	Good quality cohort	<p>Blind or independent assessment in a prospective study, or use of reliable² data in a retrospective study.</p> <p>Comparison of two or more groups must be clearly distinguished.</p> <p>Non-biased selection.</p> <p>Follow-up rate $\geq 85\%$.</p> <p>Adequate sample size.</p> <p>Statistical analysis of potential confounders.³</p>
II	Good quality case-control	<p>Accurate ascertainment of cases.</p> <p>Nonbiased selection of cases/controls with exclusion criteria applied equally to both.</p> <p>Adequate response rate.</p> <p>Appropriate attention to potential</p>

Class of Evidence	Study Design	Quality Criteria
		confounding variables.
III	Poor quality RCT	Major violations of the criteria for a good or moderate quality RCT. ¹
III	Moderate or poor quality cohort	Violation of one or more criteria for a good quality cohort. ¹
III	Moderate or poor quality case-control	Violation of one or more criteria for a good quality case-control. ¹
III	Case Series, Databases or Registries	Prospectively collected data that is purely observational, and retrospectively collected data.
<p>¹Assessor needs to make a judgment about whether one or more violations are sufficient to downgrade Class of study, based upon the topic, the seriousness of the violation(s), their potential impact on the results, and other aspects of the study. Two or three violations do not necessarily constitute a major flaw. The assessor needs to make a coherent argument why the violation(s) either do, or do not, warrant a downgrade.</p> <p>²Reliable data are concrete data such as mortality or re-operation.</p> <p>³Publication authors must provide a description of robust baseline characteristics, and control for those that are unequally distributed between treatment groups.</p>		

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Remaining blinded to each other's work, participants read each publication and abstracted data using a predetermined format.

Quality of Body of Evidence

Ultimately the individual studies were considered in aggregate, whether through meta-analyses or through qualitative assessment. Thus, the strength of recommendations were derived from the quality of the overall body of evidence used to address the topic.

The quality of the overall body of evidence for each recommendation was classified as **high**, **moderate**, or **low**. Factors that may decrease the quality include potential bias, differing findings across studies, the use of indirect evidence, or lack of precision. For example, if two or more Class I studies demonstrate contradictory findings for a particular topic, the overall quality most probably will be low because there is uncertainty about the effect. Similarly, Class I or II studies that provide indirect evidence may only constitute low quality evidence, overall.

Indirect Evidence

Well controlled studies conducted in the field are rare. One alternative is to apply evidence from studies conducted in other environments to field practice, or from other pathologies to traumatic brain injury (TBI). In this document, indirect evidence from inhospital populations or from physiological studies was used, after careful consideration of the quality of the study for its own population, and then of its usefulness as indirect evidence. The following sequential process of questions was used:

1. To what extent does the physiology of the field application approximate the physiology of the inhospital application?
2. What are the differences in patients, settings, treatments, and measurements between the field and inhospital settings?
3. To what extent would those differences influence the physiology of the intervention?
4. To what extent and in what direction would those differences influence the observed effect?
5. What is the quality of the publication?
6. Consider all of the above (1) to determine if the publication can be used as indirect evidence, and if so, (2) to determine the quality of the evidence.

In the original guideline document, indirect evidence used to support a recommendation is identified as such.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The Brain Trauma Foundation (BTF) and the BTF Center for Guidelines Management (Center) convened a virtual meeting of previous participants in the development of *Guidelines for Prehospital Management of Traumatic Brain Injury*,

as well as with colleagues new to the project. They specified topics for inclusion in the current update, and agreed to include pediatric literature as a separate section for each topic. Further refinement of topics and scope was accomplished in a subsequent work meeting of participants with BTF and Center staff. The group agreed to maintain the distinction between *Assessment* topics and *Treatment* topics.

The participants drafted chapters and the entire team gathered for a 2-day work session to discuss the literature base, and to achieve consensus on classification of quality of evidence, and strength of recommendations.

After the work meeting, participants revised each topic based on the group's recommendations. Virtual meetings were convened, during which a subset of approximately five members of the team edited each topic online.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strong recommendations are derived from high quality evidence that provide precise estimates of the benefits or downsides of the topic being assessed.

With **weak** recommendations, (1) there is lack of confidence that the benefits outweigh the downsides, (2) the benefits and downsides may be equal, and/or (3) there is uncertainty about the degree of benefits and downsides.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Final versions were circulated to the Review Committee. Critiques from the Review Committee were addressed by participants and incorporated, or not, based upon their accuracy and consistency with the pre-specified systematic process.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Strength of recommendations (**strong** or **weak**) and quality of evidence (**Class I-III**) are defined at the end of the "Major Recommendations" field.

Strength of Recommendations: Weak.

Quality of Evidence: Low, from Class III studies, or Class II studies with contradictory findings.

Adult

- A. Hypotensive patients should be treated with isotonic fluids.
- B. Hypertonic resuscitation is a treatment option for traumatic brain injury (TBI) patients with a Glasgow Coma Scale Score (GCS) ≤ 8 .

Pediatric

- A. For the pediatric TBI patient, hypotension should be treated with isotonic solutions.

Definitions:

Quality of Evidence

Class of Evidence	Study Design	Quality Criteria
I	Good quality randomized controlled trial (RCT)	Adequate random assignment method. Allocation concealment. Groups similar at baseline. Outcome assessors blinded. Adequate sample size. Intention-to-treat analysis. Follow-up rate $\geq 85\%$. Differential loss to follow-up. Maintenance of comparable groups.
II	Moderate quality RCT	Violation of one or more of the criteria for a good quality

Class of Evidence	Study Design	Quality Criteria
		RCT. ¹
II	Good quality cohort	<p>Blind or independent assessment in a prospective study, or use of reliable² data in a retrospective study.</p> <p>Comparison of two or more groups must be clearly distinguished.</p> <p>Non-biased selection.</p> <p>Follow-up rate $\geq 85\%$.</p> <p>Adequate sample size.</p> <p>Statistical analysis of potential confounders.³</p>
II	Good quality case-control	<p>Accurate ascertainment of cases.</p> <p>Nonbiased selection of cases/controls with exclusion criteria applied equally to both.</p> <p>Adequate response rate.</p> <p>Appropriate attention to potential confounding variables.</p>

Class of Evidence	Study Design	Quality Criteria
III	Poor quality RCT	Major violations of the criteria for a good or moderate quality RCT. ¹
III	Moderate or poor quality cohort	Violation of one or more criteria for a good quality cohort. ¹
III	Moderate or poor quality case-control	Violation of one or more criteria for a good quality case-control. ¹
III	Case Series, Databases or Registries	Prospectively collected data that is purely observational, and retrospectively collected data.
<p>¹Assessor needs to make a judgment about whether one or more violations are sufficient to downgrade Class of study, based upon the topic, the seriousness of the violation(s), their potential impact on the results, and other aspects of the study. Two or three violations do not necessarily constitute a major flaw. The assessor needs to make a coherent argument why the violation(s) either do, or do not, warrant a downgrade.</p> <p>²Reliable data are concrete data such as mortality or re-operation.</p> <p>³Publication authors must provide a description of robust baseline characteristics, and control for those that are unequally distributed between treatment groups.</p>		

Strength of Recommendation

Strong recommendations are derived from high quality evidence that provide precise estimates of the benefits or downsides of the topic being assessed.

With **weak** recommendations, (1) there is lack of confidence that the benefits outweigh the downsides, (2) the benefits and downsides may be equal, and/or (3) there is uncertainty about the degree of benefits and downsides.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Reduction in morbidity or mortality from severe traumatic brain injury (TBI) with prehospital hypotension management

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

The information contained in these Guidelines, which reflects the current state of knowledge at the time of completion of the literature search (July 2006), is intended to provide accurate and authoritative information about the subject matter covered. Because there will be future developments in scientific information and technology, it is anticipated that there will be periodic review and updating of these Guidelines. These Guidelines are distributed with the understanding that the Brain Trauma Foundation, the National Highway Traffic Safety Administration, and the other organizations that have collaborated in the development of these Guidelines are not engaged in rendering professional medical services. If medical advice or assistance is required, the services of a competent physician should be sought. The recommendations contained in these Guidelines may not be appropriate for use in all circumstances. The decision to adopt a particular recommendation contained in these Guidelines must be based on the judgment of medical personnel, who take into consideration the facts and circumstances in each case, and on the available resources.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Treatment: fluid resuscitation. In: Badjatia N, Carney N, Crocco TJ, Fallat ME, Hennes HM, Jagoda AS, Jernigan S, Lerner EB, Letarte PB, Moriarty T, Pons PT, Sasser S, Scalea TM, Schleien C, Wright DW. Guidelines for prehospital management of traumatic brain injury. 2nd ed. New York (NY): Brain Trauma Foundation; 2007. p. 61-70. [21 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2000 (revised 2007)

GUIDELINE DEVELOPER(S)

Brain Trauma Foundation - Disease Specific Society
National Highway Traffic Safety Administration - Federal Government Agency
[U.S.]

SOURCE(S) OF FUNDING

Brain Trauma Foundation

National Highway Traffic Safety Administration

GUIDELINE COMMITTEE

Not stated

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Authors: Neeraj Badjatia, MD; Nancy Carney, PhD; Todd J. Crocco, MD; Mary Elizabeth Fallat, MD, FACS; Halim M. A. Hennes, MD, FAAP; Andy S. Jagoda, MD,

FACEP; Sarah Jernigan, MD; E. Brooke Lerner, PhD; Peter B. Letarte, MD, FACS; Thomas Moriarty, MD; Peter T. Pons, MD, FACEP; Scott Sasser, MD; Thomas M. Scalea, MD, FACS; Charles Schleien, MD; David W. Wright, MD

Participants: John E. Campbell, MD, FACEP; Pamela Drexel, Brain Trauma Foundation; Jamshid Ghajar, MD, PhD; Lauren Post, MD; Andrew W. Stern, NREMT-P, MPA, MA

Review Committee: P. David Adelson, MD, FACS, FAAP; Arthur Cooper, MD, FACS; Thomas J. Esposito, MD, MPH, FACS; John William Jermyn, DO, FACEP; Tom Judge, CCT-P; Carsten Kock-Jensen, MD, Chair, Scandinavian Neurotrauma Committee; Jon R. Krohmer, MD, FACEP; Anthony Marmarou, PhD; Lawrence Marshall, MD; Stephan Mayer, MD; Connie A. Meyer, MICT; Robert E. O'Connor, MD, MPH, FACEP; Jeffrey P. Salomone, MD, FACS; Snorre Sollid, MD, Scandinavian Neurotrauma Committee; Andreas Unterberg, MD; Alex B. Valadka, MD, FACS; Walter Videtta, MD; Robert K. Waddell II, NAEMT; Beverly Walters, MD, FACS

Education Subcommittee: Cathy Case, EMT-P; Debra Cason, RN; John Gosford; Joseph A. Grafft; Jon R. Krohmer, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Brain Trauma Foundation. Guidelines for prehospital management of traumatic brain injury. New York (NY): Brain Trauma Foundation; 2000. 81 p.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the [Brain Trauma Foundation Web site](#).

Print copies: Available from the Brain Trauma Foundation, 708 Third Avenue, New York, NY 10017

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on June 4, 2008.

COPYRIGHT STATEMENT

This is a limited license granted to NGC, AHRQ and its agent only. It may not be assigned, sold, or otherwise transferred. BTF owns the copyright. For any other permission regarding the use of these guidelines, please contact the Brain Trauma Foundation.

DISCLAIMER

NGC DISCLAIMER

The National Guideline Clearinghouse™ (NGC) does not develop, produce, approve, or endorse the guidelines represented on this site.

All guidelines summarized by NGC and hosted on our site are produced under the auspices of medical specialty societies, relevant professional associations, public or private organizations, other government agencies, health care organizations or plans, and similar entities.

Guidelines represented on the NGC Web site are submitted by guideline developers, and are screened solely to determine that they meet the NGC Inclusion Criteria which may be found at <http://www.guideline.gov/about/inclusion.aspx>.

NGC, AHRQ, and its contractor ECRI Institute make no warranties concerning the content or clinical efficacy or effectiveness of the clinical practice guidelines and related materials represented on this site. Moreover, the views and opinions of developers or authors of guidelines represented on this site do not necessarily state or reflect those of NGC, AHRQ, or its contractor ECRI Institute, and inclusion or hosting of guidelines in NGC may not be used for advertising or commercial endorsement purposes.

Readers with questions regarding guideline content are directed to contact the guideline developer.

© 1998-2008 National Guideline Clearinghouse

Date Modified: 9/15/2008

